Attorney's Docket No.: 10274-063001 / A061 US 004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Mundy *et al.*	Art Unit	: 1644
Serial No.	: 10/086,217	Examiner	: Maher M. Haddad
Filed	: February 21, 2002	Conf. No.	: 5114
Title	: METHODS OF TREATING MULTIPLE MYELOMA AND MYELOMA-INDUCED BONE RESORPTION USING INTEGRIN ANTAGONISTS		

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DR. GREGORY R. MUNDY UNDER 37 C.F.R. §1.132

I, Gregory R. Mundy, a citizen of U.S.A., residing in Nashville, Tennessee, hereby declare as follows:

1. I am the Director of the Vanderbilt Center for Bone Biology; a Professor of Medicine, Pharmacology, Orthopedics, and Cancer Biology; and the John A. Oates Chair in Translational Medicine at Vanderbilt University in Nashville, Tennessee. I received my initial doctoral degree in Medicine and Surgery from the University of Melbourne in Australia and my second degree in Medicine from the University of Tasmania in Australia, and I did postdoctoral work at the University of Rochester in New York. I have over 35 years experience in the field of bone disease. I have published over 540 scientific articles, including 2 articles specifically on integrin studies. A copy of my CV is attached.

2. I have reviewed the above-referenced patent application and the references discussed herein.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date of Deposit

Signature

Typed or Printed Name of Person Signing Certificate

3. I have been advised and understand that the Examiner has rejected claims 86-89, 91, 93-97, and 101, which are directed to methods of treating multiple myeloma with an anti-I4 integrin antibody and a chemotherapeutic agent, as being unpatentable over Van Zaanen *et al.*, *Br. J. Haematol.* 102:783-790, 1998 ("Van Zaanen") in view of Masellis-Smith *et al.*, *Cancer Res.* 57:930-936, 1997 ("Masellis-Smith") and Lokhorst *et al.*, *Blood* 84:2269-2277, 1994 ("Lokhorst") and U.S. Patent No. 5,885,786 (1996) ("Cabot") or Alexanian *et al.*, *J. Am. Med. Assoc.* 208:1580-2685, 1969 ("Alexanian"). The Examiner argues that, at the time of priority (September 13, 1999), one of ordinary skill in the art would have been motivated to substitute anti-I4 antibodies for the anti-IL-6 antibodies taught by Van Zaanen, and to further combine the anti-α4 antibody with the chemotherapeutic agent melphalan, as taught by Cabot and Alexanian, for the treatment of multiple myeloma (MM).

4. At the time of filing, a practitioner of ordinary skill in this field would not, for numerous reasons, have believed that anti-α4 antibodies, such as anti-VLA-4 antibodies, would be interchangeable with anti-IL-6 antibodies to treat MM. First, the art did not teach the anti-IL-6 antibodies could be used to treat MM. For example, Bataille *et al.* ("Biological Effects of Anti-Interleukin-6 Murine Monoclonal Antibody in Advanced Multiple Myeloma" *Blood* 86:685-691, 1995; cited in the IDS submitted June 21, 2002; courtesy copied enclosed as Exhibit A) taught that anti-IL6 antibodies were not effective at treating MM. Bataille *et al.* reported that patients with advanced MM did not achieve remission or improved outcome following treatment with murine anti-IL6 monoclonal antibodies. Van Zaanen, which is relied upon by the Examiner, is a phase I dose-escalating study that, at best, shows that anti-IL-6 antibodies are not toxic. None of the patients involved in the study achieved a response according to standard criteria, even though effective IL-6 blocking was detected in 11/12 patients. See Van Zaanen in the abstract and in the discussion at page 787. The teachings of Van Zaanen do not overcome or refute the prior teachings of Bataille *et al.* that anti-IL-6 antibodies are ineffective for the treatment of MM. Evidence that anti-VLA-4 antibodies decreased tumor burden *in vivo* in a mouse model of myeloma bone disease is presented in the

above-referenced application (see, *e.g.*, page 66, lines 14-26), and the results of these studies were published in Mori *et al.* ("Anti-α4 integrin antibody suppresses the development of multiple myeloma and associated osteoclastic osteolysis," *Blood* 104:2149-2154, 2004, cited in the information disclosure statement (IDS) submitted herewith).

5. The Examiner has cited Lokhorst *et al.* as evidence that anti-VLA-4 antibodies inhibited IL-6 secretion *in vitro* by long term bone marrow cultures (LTBMCs) contacted with MM cells. The Examiner has considered this evidence in combination with Van Zaanen and Masellis-Smith to conclude that anti-VLA-4 antibodies can be used for the treatment of MM. One of ordinary skill in this field, however, would not arrive at this conclusion. In view of the fact that anti-VLA-4 antibodies decrease tumor burden in mouse models of myeloma bone disease, and that anti-IL-6 is not effective as a treatment for myeloma[1] (see paragraph 4), one of ordinary skill in this field would conclude that although anti-VLA4 antibodies can decrease IL-6 levels (at least *in vitro*), this does not appear to be relevant to the anti-tumor effect of the anti-VLA-4 antibodies. Anti-VLA-4 antibodies are believed to work through mechanisms that are independent of IL-6. Anti-VLA-4 antibodies kill myeloma cells by blocking direct interactions between myeloma cells and normal host cells in the bone marrow. When the myeloma cells cannot attach to the normal host cells, the myeloma cells die. There may be a concomitant decrease in IL-6 levels following administration of anti-VLA-4, but this is a byproduct and not the direct cause of myeloma cell death, nor the reason why the myeloma cells die.

6. At the time of filing, a practitioner of ordinary skill in this field would not have believed that anti-VLA-4 antibodies could substitute for the prednisone taught by Alexanian *et al.* in a combination therapy with melphalan for the treatment of MM. One of ordinary skill in the art would not make this substitution at least because anti-VLA4 antibodies and prednisone

[1] Batialle *et al.* report that some MM patients experienced improvements in some symptoms following treatment with a murine anti-IL-6 monoclonal antibody. For example, of the 3 patients who succumbed to progressive MM after less than 1 week of treatment, 2 exhibited marked inhibition of plasmablastic proliferation. Of the seven remaining patients, 3 had objective antiproliferative effect marked by a significant reduction of the myeloma cell labeling index within the bone marrow. One of these 3 patients received a 30% regression of tumor mass. The authors concluded, however, that none of the patients studied achieved remission or improved outcome as judged by standard clinical criteria. See Bataille *et al.* in the abstract.

are different types of molecules having different therapeutic targets, and therefore different therapeutic effects. As described in paragraph 5, anti-VLA4 antibodies are very specific targeting molecules that kill myeloma cells by blocking direct interactions between myeloma cells and normal host cells in the bone marrow. Prednisone is a broad spectrum agent which kills cancer cells regardless of whether or not they are interacting with other cells. Thus whether prednisone and melphalan in combination can be used to treat MM (as described in Alexanian) is irrelevant insofar as predicting whether a combination of an anti-VLA-4 antibody and melphalan can be used to treat MM. Even in view of Van Zaanen, Masellis-Smith, and Lokhorst, a therapeutic effect of a combination therapy of prednisone and melphalan for treatment of MM is not predictive of a therapeutic effect of a combination therapy of anti-VLA-4 antibodies and melphalan.

7. Evidence that an anti-IL6 receptor antibody in combination with melphalan can treat MM, as described in Nakamura (U.S. Patent No. 6,692,742) is also irrelevant insofar as predicting whether a combination of an anti-VLA-4 antibody and melphalan can be used to treat MM. An anti-IL6 receptor antibody will disrupt a multitude of pathways, as this receptor interacts with a class of ligands called gp130 ligands and gp80 ligands. See, *e.g.*, Schwabe *et al., J. Biol. Chem.* 269:7201-7209, 1994, cited on the attached IDS. Thus in view of evidence that a combination of anti-IL-6 receptor antibodies and melphalan can treat MM, one of skill in the art would not conclude that an anti-VLA-4 antibody (which disrupts a very different interaction) in combination with a chemotherapeutic agent would also be effective for the treatment of MM. As described in paragraph 5, studies described in the prior art indicate that anti-VLA-4 antibodies kill myeloma cells through a mechanism that is independent of IL-6.

8. A combination of melphalan and anti-VLA-4 antibody was observed to have a synergistic effect on the treatment of MM (see the specification at page 72, lines 6-20). As shown in Figure 8 of the specification, treatment with antibody alone (200 μg initial dose for the first week, followed by a maintenance dose of 100 μg) reduced IgG2b levels from about 2.7 mg/mL to about 2 mg/mL, and treatment with melphalan alone (100 μg) similarly reduced IgG2b levels from about 2.7 mg/mL to about 2 mg/mL. However, treatment with the

combination of antibodies and melphalan resulted in a much more significant decrease in IgG2b levels (from about 2.7 mg/mL to about 0.3 mg/mL). The effect of IgG2b levels is indicative of a decrease in tumor burden. The synergistic result observed with the combination of melphalan and anti-VLA-4 was unexpected and surprising because there was no reason to expect such a dramatic improvement in view of the mild effects observed with either melphalan or antibody alone.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

DATE: Sept 11, 2006

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(9/07/06) CURRICULUM VITAE

MUNDY, Gregory Robert

Office Telephone - 615-322-6110

Citizenship - Dual (United States, Australia)

Secondary Education

1956-60 Trinity Grammar School, Kew, Victoria, Australia

Tertiary Education, Degrees, and Diplomas

1961-66 MB; BS (Bachelor of Medicine, Bachelor of Surgery), University of Melbourne

1966 E.C.F.M.G. (Certificate of Education Council for Foreign Medical Graduates)

1970 M.R.A.C.P. (Membership of Royal Australian College of Physicians)

1973 Doctor of Medicine, University of Tasmania

1974 FLEX (Federal Licensing Examinations)

1974 F.R.A.C.P. (Fellowship of Royal Australasian College of Physicians)

1975 Diplomate, American Board of Internal Medicine

1977 Diplomate, Subspecialty Boards in Endocrinology and Metabolism

Medical Licensure

Victoria, Australia	
Tasmania, Australia	
New York, U.S.A.	122297
Connecticut, U.S.A.	17068
Texas, U.S.A.	F-7583
United Kingdom	

Professional Societies and Organizations

Advisory Council, National Institute of Arthritis, Musculoskeletal and Skin Diseases (1997-2001)
American Society for Clinical Investigation
Association of American Physicians
American Society for Clinical Pharmacology and Therapeutics
American Society for Bone and Mineral Research
- Councilor, 1983-1985, 1995-1998
- Secretary-Treasurer, 1985-1991
- President, 1996-1997

Association of GCRC Program Directors
- Councilor, 1987-1989
Endocrine Society
American Association for the Advancement of Science
American Federation for Clinical Research
European Calcified Tissue Society
- Board Member, 1987-1988
Fellow, Royal Australasian College of Physicians
International Bone and Mineral Society
- Board of Directors, 1992-2001
- Vice President and President-Elect, 2001-2003
- President, 2003-2005
National Osteoporosis Foundation
- Scientific Advisory Board, 1985-
- Chairman, Research Grants Committee, 1988-1996
- Executive Committee, Scientific Advisory Board, 1991-1996
- Board of Trustees, 1996-
The Paget Foundation
- Scientific Advisory Board, 1991-
Southern Society for Clinical Investigation
- President, 1990
International Myeloma Foundation
- Scientific Advisory Board, 1993-
- Board of Directors, 1997-
CTRC Clinical Foundation Board of Trustees, 2000-2002
CTRC Research Foundation Board of Trustees, 2001-2002
SACI Executive Committee, 2002-2005

Experience

1/67-12/67	Junior Resident Medical Officer, Royal Hobart Hospital, Hobart, Tasmania
1/68-12/68	Senior Resident Medical Officer, Royal Hobart Hospital, Hobart, Tasmania
1/69-9/70	Professorial Medical Registrar, Royal Hobart Hospital, Hobart, Tasmania
10/70-8/72	Lecturer in Medicine, University of Tasmania, and Honorary Physician, Royal Hobart Hospital
8/72-5/74	Research Associate in Clinical Pharmacology, Department of Pharmacology and Toxicology, University of Rochester, Rochester, New York
5/74-6/77	Assistant Professor of Medicine, Division of Endocrinology and Metabolism, University of Connecticut School of Medicine, Farmington, CT
6/77-6/80	Associate Professor of Medicine, Division of Endocrinology and Metabolism, University of Connecticut School of Medicine, Farmington, CT
7/80-10/01	Professor of Medicine and Head, Division of Endocrinology and Metabolism, University of

Texas Health Science Center at San Antonio, Texas

3/82-1/00 Program Director, General Clinical Research Center, The University of Texas Health Science Center at San Antonio, Texas and Chief, Frederic C. Bartter Clinical Research Unit, Audie L. Murphy Memorial Veterans' Hospital, San Antonio, Texas

7/88-12/95 President and Scientific Director, OsteoSA Corporation, San Antonio, Texas

1/96- President and Scientific Director, OsteoScreen Inc., San Antonio, Texas

3/96-10/01 J.C. and Irene H. Heyser Memorial Professor of Bone and Mineral Metabolism, University of Texas Health Science Center at San Antonio, San Antonio, TX

6/99- Adjunct Professor of Medicine, University of Queensland, Brisbane, Australia.

10/00-6/06 Assistant Dean for Clinical Research, University of Texas Health Science Center at San Antonio, TX

6/01-9/02 SBC Chair in Cancer Research and Director, CTRC Institute for Drug Development, San Antonio, Texas

10/01-6/06 Assistant Dean for Clinical Research, UTHSCSA, San Antonio, Texas

9/04-9/05 Director of Orthopedic Research, University of Texas Health Science Center at San Antonio, San Antonio, TX

3/05-9/05 Principal Investigator, Cancer Center Support Grant, San Antonio Cancer Institute, University of Texas Health Science Center at San Antonio, TX

9/02-6/06 Professor, Department of Cellular & Structural Biology, University of Texas Health Science Center at San Antonio, San Antonio, TX

7/06- Director, Vanderbilt Center for Bone Biology, Professor of Medicine, Pharmacology, Orthopaedics, and Cancer Biology, Vanderbilt University, Nashville, TN

7/06- John A. Oates Chair in Translational Medicine, Vanderbilt University, Nashville, TN

Company Affiliations

Osteo SA CEO and President 1987-1995. Osteo SA was formed as a private spinoff from the bone biology group in the Endocrine Division at the University of Texas Health Science Center and in collaboration with ?????. It was a service-based company that raised $10m in support.

OsteoScreen CEO and President 1996- OsteoScreen was the successor of Osteo SA. It has raised over $25m from license deals, research contracts and SBIR grants.

NEOSIL Member, Board of Directors 2005 Neosil is a start-up specialty pharmaceutical company in Emergyville, CA. It licensed one of OsteoScreen's assets. OsteoScreen is a major shareholder in Neosil.

OsteoGenix CSO and Member, Board of Directors 2006 OsteoGenix is a start-up specialty pharmaceutical company based in Palo Alto, CA. It licensed one of OsteoScreen's assets.

Special Awards

American Cancer Society Faculty Research Award FRA-148, 1976-1981

Fuller Albright Award of the American Society for Bone and Mineral Research, 1982

MERIT Award from National Institutes of Health for grant AR28149 "The Monocyte-Macrophage System and Bone Resorption", 1986-1996

William F. Neuman Award of American Society for Bone and Mineral Research, 1999

University of Texas Presidential Distinguished Scholar, 1999

Editorial Boards

Bone
Calcified Tissue International
Journal of Clinical Endocrinology and Metabolism (1983-1988)
Journal of Bone and Mineral Research (1986-1993)
American Journal of Medical Sciences (1990-1998)
Journal of NIH Research (1989-1997)
Journal of Biological Chemistry (1997-1999)
Journal of Internal Medicine (2000-)

Peer Review Groups

Member, General Medicine B Study Section, 1981-1985

OsteoScreen, Ltd. Patents

US Patent No.:	5,599,708
Title:	Osteoclast Growth Regulatory Factors
Issue Date:	February 4, 1997
US Patent No.:	5,614,496
Title:	Use of Fibroblast Growth Factors to Stimulate Bone Growth
Issue Date:	March 25, 1997
US Patent No.:	5,656,598
Title:	Use of Fibroblast Growth Factors to Stimulate Bone Growth
Issue Date:	August 12, 1997
US Patent No.:	5,914,233
Title:	Screening Assay for the Identification of Agents Which Alter Expression of

PTHrP
Issue Date: June 22, 1999

US Patent No.: 5,919,808
Title: Compositions and Methods for Treating Bone Deficit Conditions
Issue Date: July 6, 1999

US Patent No.: 5,922,753
Title: Methods for Treating Bone Deficit Conditions with Benzothiazole
Issue Date: July 13, 1999

US Patent No.: 5,939,444
Title: Compositions and Methods for Treating Bone Deficit Conditions
Issue Date: August 17, 1999

US Patent No.: 5,948,776
Title: Compositions and Methods for Treating Bone Deficit Conditions
Issue Date: September 7, 1999

US Patent No.: 5,965,573
Title: Compositions and Methods for Treating Bone Deficit Conditions
Issue Date: October 12, 1999

Australian Patent: 706262
Title: Compositions and Methods for Treating Bone Deficit Conditions
Issue Date: September 23, 1999

US Patent No: 5,990,169
Title: Compositions and Methods for Treating Bone Deficit Conditions
Issue Date: November 23, 1999

US Patent No: 5,994,358
Title: Compositions and Methods for Treating Bone Deficit Conditions
Issue Date: November 30, 1999

US Patent No: 6,008,208
Title: Compositions and Methods for Treating Bone Deficit Conditions
Issue Date: December 28, 1999

US Patent No: 6,017,940
Title: Compositions and Methods for Treating Bone Deficit Conditions
Issue Date: January 25, 2000

US Patent No: 6,022,887
Title: Compositions and Methods for Stimulating Bone Growth
Issue Date: February 8, 2000

US Patent No: 6,060,500
Title: Suppression, by 5-lipoxygenase inhibitors, of bone resorption
Issue Date: May 9, 2000

US Patent No:	6,083,690
Title:	Methods and Compositions for Identifying Osteogenic Agents
Issue Date:	July 4, 2000
US Patent No:	6,080,779
Title:	Compositions and Methods for Stimulating Bone Growth
Issue Date:	June 27, 2000
US Patent No:	6,153,631
Title:	Compositions and Methods for Treating Bone Deficit Conditions
Issue Date:	November 28, 2000
US Patent No:	6,251,901
Title:	Compositions and Methods for Treating Bone Deficit Conditions
Issue Date:	June 26, 2001
US Patent No:	6,342,514 B1
Title:	Compositions and Methods for Treating Bone Deficit Conditions
Issue Date:	January 29, 2002
US Patent No:	6,376,476 B1
Title:	Isoprenoid Pathway Inhibitors for Stimulating Bone Growth
Issue Date:	April 23, 2002
US Patent No:	6,410,512 B1
Title:	Inhibitors of Proteasomal Activity for Stimulating Hair Growth
Issue Date:	June 25, 2002
US Patent No:	6,410,521 B1
Title:	Nutritional Supplements for Stimulating Bone Growth
Issue Date:	June 25, 2002
US Patent No:	6,413,998
Title:	Compositions and Methods for Treating Bone Deficit Conditions
Issue Date:	July 2, 2002
US Patent No:	6,462,019
Title:	Inhibitors of Proteasomal Activity and Production for Stimulating Bone Growth
Issue Date:	October 8, 2002
US Patent No:	6,492,333
Title:	Treatment of Myeloma Bone Disease with Proteasomal Inhibitors
Issue Date:	December 10, 2002
US Patent No:	6,642,216
Title:	A Method to Identify Compounds for Treating Bone Disorders
Issue Date:	November 4, 2003
US Patent No:	6,649,631
Title:	Compositions and Methods for Treating Bone Deficit Conditions

Issue Date:	November 18, 2003
US Patent No:	6,656,904
Title:	Inhibitors of Proteasomal Activity for Stimulating Bone and Hair Growth
Issue Date:	December 2, 2003
US Patent No:	6,720,344
Title:	Methods and Compositions for Stimulating Osteoblast Proliferation or Treating Malignant Cell Proliferation and Methods for Selecting Osteoblast Proliferation Stimulants
Issue Date:	April 13, 2004
Australian Patent:	771297
Title:	Inhibitors of Proteasomal Activity for Stimulating Bone and Hair Growth
Issue Date:	July 8, 2004
US Patent No:	6,838,252
Title:	Inhibitors of Proteasomal Activity for Stimulating Hair Growth
Issue Date:	January 4, 2005
US Patent No:	6,838,436
Title:	Inhibitors of Proteasomal Activity for Stimulating Bone Growth
Issue Date:	January 4, 2005
US Patent No:	6,884,769
Title:	Inhibitors of Proteasomal Activity for Stimulating Hair Growth (as Amended)
Issue Date:	April 26, 2005
US Patent No:	6,902,721
Title:	Inhibitors of Proteasomal Activity for Stimulating Bone Growth
Issue Date:	June 7, 2005
US Patent No:	6,958,220
Title:	Inhibitors of Proteasomal Activity for Stimulating Hair Growth
Issue Date:	October 25, 2005
Australian Patent:	784304
Title:	Inhibitors of Proteasomal Activity for Stimulating Bone and Hair Growth
Issue Date:	March 9, 2006

The University of Texas Health Science Center at San Antonio Patents

US Patent No:	5,534,524
Title:	Suppression by 5-Lipoxygenase Inhibitors of Bone Resorption
Issue Date:	July 9, 1996
US Patent No:	6,060,500
Title:	Suppression by 5-Lipoxygenase Inhibitors of Bone Resorption
Issue Date:	May 9, 2000

US Patent No:	6,455,541 B1
Title:	Suppression by 5-Lipoxygenase Inhibitors of Bone Resorption
Issue Date:	September 24, 2002
South African Patent No:	2001/2032
Title:	Methods of Treating Multiple Myeloma and Myeloma-Induced Bone Resorption Using Integrin Antagonists
Issue Date:	January 29, 2003
Eurasian Patent No:	004270 based on PCT/US99/21170
Title:	Methods of Treating Multiple Myeloma and Myeloma-Induced Bone Resorption Using Integrin Antagonists
Issue Date:	February 26, 2004
Singapore Patent No:	79378 based on PCT/US99/21170
Title:	Methods of Treating Multiple Myeloma and Myeloma-Induced Bone Resorption Using Integrin Antagonists
Issue Date:	May 31, 2004

Grant Support

"Effects of Tumors on the Skeleton"
Principal Investigator: Gregory R. Mundy, M.D
Program Director: Gregory R. Mundy, M.D.
Agency: NIH, NCI
Type: 2-P01-CA40035
Period: 12/1/05-11/30/10
Total: $958,420 (annual direct costs)

"Mechanism of Action of Statins on Bone Formation"
Principle Investigator: Gregory R. Mundy, M.D.
Agency: Veterans Administration
Type: Merit Review
Period: 4/1/03-3/31/08
Total: $135,000 (annual direct costs)

"Effects of the Mevalonate Pathway on Bone Formation"
Principle Investigator: Gregory R. Mundy, M.D.
Agency: NIH
Type: RO1 AR048801-01
Period: 5/1/03-4/30/08
Total: $201,213 (annual direct costs)

"Gli Control of PTH-rP and Osteolysis in Breast Cancer"
Principal Investigator: Gregory R. Mundy, M.D
Agency: NIH, NCI
Type: R01 CA114000-01
Period: 7/18/05-4/30/10

Total: $192,859 (annual direct costs)

"Ubiquitin-Proteasome Pathway and BMP-2 Expression"
Principal Investigator: Gregory R. Mundy, M.D
Agency: NIH, NIAMS
Type: R01 AR050605-01-A1
Period: 9/1/05-6/30/09
Total: $176,000 (annual direct costs)

"Health Care and Other Facilities"
Principal Investigator: Gregory R. Mundy, M.D
Agency: HHS; Health Resources and Services Administration
Type: CFDA number 93.887
Application number: 00016419; Award number: 2C76HF03583-02-00
Period: 9/1/04-8/31/06
Total: $492,080 (annual direct costs)

"OsteoScreen" (G.R. Mundy, M.D.)
OsteoScreen Ltd. is a small start-up biotechnology company whose goal is to develop anabolic agents for osteoporosis. Dr. Mundy is a consultant and director of research programs at OsteoScreen. It is supported by license payments, private funds and research contracts from pharmaceutical companies and NIH SBIR grants.

Bibliography

Dr. Mundy is the author of over 545 original articles, review articles and book chapters. He has published 2 monographs and edited 2 books.
Publications (*indicates those article which were peer reviewed)

* 1. Cutforth R, Mitchell RM, Mundy GR: Cytomegalovirus mononucleosis following renal haemodialysis. Med J Aust 2:1103-1104, 1968.

* 2. Freeman JW, Mundy GR, Beattie RR, Ryan CR: Cardiac abnormalities in poisoning with tricyclic antidepressants. Brit Med J 2:610-611, 1969.

3. Baikie AG, MacDonald CB, Mundy GR: Systemic nocardiosis treated with trimethoprim and sulphamethoxazole. Lancet 2:261, 1970.

* 4. Mundy GR: Infectious mononucleosis with pulmonary parenchymal involvement. Brit Med J 1:219-220, 1972.

* 5. Mundy GR, Cutforth RH: The relationship between serum lipid abnormalities and other major risk factors in myocardial infarction. Aust N Z J Med 1:8-12, 1972.

* 6. Mundy GR, Cutforth RH, Brooks PM: Serum lipid abnormalities and the atrial pacing test. Med J Aust 2:535-537, 1972.

* 7. Mundy GR, MacDonald CB: Atypical presentations of diffuse fibrosing alveolities. Brit J Dis Chest

66:261-267, 1972.

* 8. Mundy GR: Cytogenic Studies and DNA Content in Myeloma, With Reference to Other Features of the Disease. M.D. Thesis, University of Tasmania, 1972.

* 9. Mundy GR, McPherson DG: Variation in serum cholesterol levels after myocardial infarction. Med J Aust 1:278-282, 1973.

* 10. Mundy GR, Baikie AG: Myeloma treated with cyclophosphamide and terminating in reticulum cell sarcoma. Med J Aust 1:1240-1241, 1973.

* 11. Dartnall JA, Mundy GR, Baikie AG: Cytogenetic studies in myeloma. Blood 42:229-239, 1973.

* 12. Mundy GR: DNA values in myeloma. Cancer 32:61-68, 1973.

13. Raisz LG, Mundy GR, Luben RA: Skeletal reactions to neoplasms. Ann N Y Acad Sci 230:473-475, 1974.

* 14. Luben RA, Mundy GR, Trummel CL, Raisz LG: Partial purification of osteoclast-activating factor from phytohemagglutinin-stimulated human leukocytes. J Clin Invest 53:1473-1480, 1974.

* 15. Mundy GR, Fleckenstein L, Mazzullo JM, Sundararesan P, Weintraub M, Lasagna L: Current medical practice and the FDA; Some evidence for the existing gap. JAMA 229:1744-1748, 1974.

* 16. Mundy GR, Luben RA, Raisz LG, Oppenheim JJ, Buell DN: Bone-resorbing activity in supernatants from lymphoid cell lines. N Engl J Med 290:867-871, 1974.

* 17. Mundy GR, Raisz LG, Cooper RA, Schechter GP, Salmon SE: Evidence for the secretion of an osteoclast stimulating factor in myeloma. N Engl J Med 291:1041-1046, 1974.

18. Mundy GR, Raisz LG: Drugs for disorders of bones: Pharmacological and clinical considerations. Drugs 8:250-289, 1974.

19. Mundy GR, Raisz LG: Drugs for disorders of bones. New Ethic Med Prog 11:165-199, 1974.

20. Mundy GR, Raisz LG: Calcitonin: Background and uses. Drug Ther 38-42, April 1975.

21. Raisz LG, Trummel CL, Mundy GR, Luben RA: Immunologic factors influencing bone resorption: Role of osteoclast activating factor from human lymphocytes and complement-mediated prostaglandin synthesis. Proceedings of the 5th International Parathyroid Conference, Oxford, (Excerpta Medica) pp. 149-153, 1974.

* 22. Raisz LG, Luben RA, Mundy GR, Dietrich JW, Horton JE, Trummel CL: Effect of osteoclast activating factor from human leukocytes on bone metabolism. J Clin Invest 56:408-413, 1975.

* 23. Trummel CL, Mundy GR, Raisz LG: Release of osteoclast activating factor by normal human peripheral blood leukocytes. J Lab Clin Med 85:1001-1007, 1975.

24. Mundy GR, Raisz LG: Applied pharmacology of anti-hypertensive drugs. Conn Medicine 40:169-174, 1976.

* 25. Mundy GR, Shapiro JL, Bandelin JG, Canalis EM, Raisz LG: Direct stimulation of bone resorption

by thyroid hormones. J Clin Invest 58:529-534, 1976.

26. Raisz LG, Mundy GR, Dietrich JW, Canalis EM: Hormonal regulation of mineral metabolism. Int Rev Physiol 16:199-242, 1977.

* 27. Gailani S, McLimans WF, Mundy GR, Nussbaum A, Roholt O, Zeigel R: Controlled environment culture of bone marrow explants from human myeloma. Cancer Res 36:1299-1304, 1976.

* 28. Fleckenstein L, Mundy GR, Horovitz RA, Mazzullo JM: Sodium salicylamide: Relative bioavailability and subjective effects. Clin Pharm Ther 19:451-458, 1976.

29. Mundy GR, Canalis EM, Raisz LG: Modern concepts of calcium homeostasis. Conn Med 40:680-684, 1976.

30. Mundy GR, Canalis EM, Raisz LG: Osteopenia: Osteoporosis, osteomalacia, and other forms of decreased mineralized bone mass. Conn Med 40:753-757, 1976.

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